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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/413,887	10/06/1999	JOEL QUAID	35871/MAK/M4	2542
7590 03/13/2006				
HOGAN & HARTSON LLP 875 Third Avenue New York, NY 10022			EXAMINER ISABELLA, DAVID J	
			ART UNIT 3738	PAPER NUMBER
DATE MAILED: 03/13/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/413,887	Applicant(s) QUAID, JOEL	
	Examiner DAVID J. ISABELLA	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13-15,17-19,21-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Gogolewski (4834747).

Gogolewski discloses a silicone elastomer shell comprising a substantially homogeneous silicone elastomer flexible shell having interior and opposite exterior surfaces. The shell comprising at least a base layer of silicone elastomer and an outer layer of silicone elastomer. The outer layer having a rough textured surface comprising randomly formed inter-connected cells of varying diameter and located at and near the surface to simulate an open cell foam.

Claim 14, see column 3, lines 40+.

Claim 15, see column 3, lines 25+.

Claim 17, see column 3.

Claim 18, see column 3, lines 40+.

Claim 19, see column 3, lines 25+.

Claims 21-24, see rejection to the claims supra.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gogolewski (4834747) in view of Brauman (4648880).

Gogolewski discloses a silicone elastomer shell comprising a substantially homogeneous silicone elastomer flexible shell having interior and opposite exterior surfaces. The shell comprising at least a base layer of silicone elastomer and an outer layer of silicone elastomer. The outer layer having a rough textured surface comprising randomly formed inter-connected cells of varying diameter and located at and near the surface to simulate an open cell foam. While Gogolewski does not disclose the specific use of the material as a mammary prosthesis, Brauman teaches similar device as disclosed by Gogolewski and its use as soft tissue mammary implant. It would have been obvious at the time of the invention thereof to use the material of Gogolewski as a soft tissue implant including as mammary implants especially to provide a unitary construction that would prevent and/or reduce the incidence of capsular contraction. While it is not clear if the device of Gogolewski is vulcanized, the resulting material of Gogolewski is identical to that as claimed by applicant ie. a substantially homogeneous silicone elastomer flexible shell of unitary construction comprising at least a base layer and an outer layer.

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Claims, 2,4,7 and 10, see column 3, lines 40+.

Claim 11, see column 3, lines 25+.

Claim 12, though there is no specific disclosure of the depth of the interconnected cells to be about 1800 microns, Gogolewski does provide the teachings of forming multilayered material wherein there may be up to 100 layers making up the material. Using the pore size chart in column 3, it can be seen that depending on the thickness of each layer and the concentration by weight, one may have a multilayered material comprising interconnected cells to a depth of about 1800 microns.

Claim 14, see column 3, lines 40+.

Claim 15, see column 3, lines 25+.

Claim 16, though there is no specific disclosure of the depth of the interconnected cells to be about 1800 microns, Gogolewski does provide the teachings of forming multilayered material wherein there may be up to 100 layers making up the material. Using the pore size chart in column 3, it can be seen that depending on the thickness of each layer and the concentration by weight, one may have a multilayered material comprising interconnected cells to a depth of about 1800 microns.

Claim 17, see column 3.

Claim 18, see column 3, lines 40+.

Claim 19, see column 3, lines 25+.

Claim 20, though there is no specific disclosure of the depth of the interconnected cells to be about 1800 microns, Gogolewski does provide the teachings of forming multilayered material wherein there may be up to 100 layers making up the

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material. Using the pore size chart in column 3, it can be seen that depending on the thickness of each layer and the concentration by weight, one may have a multilayered material comprising interconnected cells to a depth of about 1800 microns.

Claims 21-24, see rejection to the claims supra and column 5, lines 50+..

Claim 25, though there is no specific disclosure of the depth of the interconnected cells to be about 1800 microns, Gogolewski does provide the teachings of forming multilayered material wherein there may be up to 100 layers making up the material. Using the pore size chart in column 3, it can be seen that depending on the thickness of each layer and the concentration by weight, one may have a multilayered material comprising interconnected cells to a depth of about 1800 microns.

Response to Arguments

Applicant's arguments filed 1/13/2005 have been fully considered but they are not persuasive. The amendment to the claims are directed to a method step. The preamble of the claim is directed to a product. Examiner agrees with applicant's arguments that Gogolewski does not describe or suggest the use of solid particle dissolution. However, it appears that the product as set forth in the claims is the same as the product of the prior art and therefore the claims are unpatentable even though the prior art product was made by a different process. See MPEP below.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was

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"The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983) (The claims were directed to a zeolite manufactured by mixing together various

Conclusion

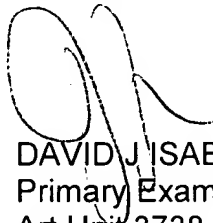
Applicant argues that Gogolewski discloses a precipitation method and the method does not yield the homogenous silicone elastomer shell as claimed. Applicant point to a Declaration submitted under 37 C.F.R. 1.132, however no such Declaration was filed concurrently with applicant's response. Accordingly, without such Declaration, the rejection is maintained and the claims stand rejected as being anticipated by Gogolewski.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J. ISABELLA
Primary Examiner
Art Unit 3738

DJI
3/4/2006